

# Quality Assurance Specialist, Batch Disposition

Job ID

REQ-10087944

Sep 23, 2026

LOC\_US

## About the Role

Location:

- This position will be located in Durham, NC and will be an onsite role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Shift:

- We currently have two openings one first-shift role and one second-shift role (starting at 12:00 PM). Both positions are scheduled Monday through Friday.

Key Responsibilities:

- Lead batch record review and batch disposition activities to support timely product release.
- Make quality-based disposition decisions for raw materials, consumables, intermediates, and finished product.
- Partner with Manufacturing and Quality teams to ensure GMP compliance throughout production operations.
- Support release of clinical and commercial products in accordance with regulatory requirements.
- Issue and manage batch records and associated manufacturing documentation.
- Review, author, and approve SOPs, work instructions, specifications, and other controlled documents.
- Drive investigations, deviations, CAPAs, and Change Controls impacting product quality and release.
- Support internal audits, regulatory inspections, and ongoing FDA inspection readiness activities.
- Monitor quality metrics and contribute to Quality Management Review reporting and site performance initiatives.
- Identify and implement continuous improvement opportunities that strengthen Quality Systems and operational effectiveness.

Essential Requirements:

- Bachelor's degree in Biology, Engineering, Microbiology, Chemistry, Biochemistry, or a related scientific discipline.
- Minimum 5 years of experience in Batch Disposition and/or Quality Assurance within a GMP-regulated environment.
- Proven experience performing batch record review and supporting product release activities.
- Strong knowledge of GMP regulations and quality systems within the biopharmaceutical industry.
- Experience supporting manufacturing operations, including cell culture, purification, or aseptic fill-finish processes.
- Demonstrated experience managing deviations, CAPAs, and Change Controls.
- Experience supporting regulatory inspections and health authority audits, including FDA inspections.
- Strong attention to detail, sound quality judgment, and the ability to manage competing priorities in a fast-paced environment.
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Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$43.00 and \$80.00 per hour

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

#LI-Onsite

## Role Requirements

Division

DIV\_TO

Business Unit

Quality

Location

LOC\_US

Site

Durham

Company / Legal Entity

U473 (FCRS = US473) Novartis Innovative Technologies Inc

Functional Area

FCT\_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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